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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/820,202	04/08/2004	Pierre Broun	056100-5005-01-US	7462

9629 7590 04/10/2007  
MORGAN LEWIS & BOCKIUS LLP  
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WASHINGTON, DC 20004

EXAMINER
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MC ELWAIN, ELIZABETH F

ART UNIT	PAPER NUMBER
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1638

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/10/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

10/820,202

Applicant(s)

BROUN ET AL.

Examiner

Elizabeth F. McElwain

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 January 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 35,38,39 and 42-50 is/are pending in the application.
- 4a) Of the above claim(s) 35,38,39,42 and 49 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 43-48 and 50 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>1/12/07</u> . | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

The amendment filed January 12, 2007 has been entered.

Claims 1-34, 36, 37, 40 and 41 are cancelled.

Claims 43-50 are newly submitted.

#### *Claim Rejections - 35 USC § 112*

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 43-48 and 50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 43-48 and 50 are indefinite in that the nucleic acid of the claims encodes a "mutant" form of a fatty acid desaturase. However, mutant is a relative term in that any sequence that differs from a wild type sequence may be considered a mutant sequence, but the present claims do not recite what would be considered the wild type sequence that would then define mutant sequences that differ from the wild type.

#### *Election/Restrictions*

1. Applicant's election with traverse of Group II in the reply filed on January 12, 2007 is acknowledged. The traversal is on the ground(s) that the methods of Groups I and II are both methods comprising transforming a plant with a nucleic

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acid encoding a fatty acid hydroxylase and would not be a serious burden to search.

This is not found persuasive because the invention of Group I is drawn to

transforming a plant with a nucleic acid encoding a fatty acid hydroxylase.

However, the invention of Group II is drawn to a method comprising transforming a

plant with a nucleic acid encoding a fatty acid desaturase which would require a

different search. The Examiner maintains that it would be a serious burden to

search and examine both inventions, wherein each requires a different nucleic acid

sequence encoding functionally distinct enzymes.

The requirement is still deemed proper and is therefore made FINAL.

Please note that claim 49 is drawn to a method of using a hydroxylase coding sequence. Therefore, claim 49 is withdrawn as drawn to a non-elected invention.

Claims 43-48 and 50 are drawn to the elected invention and are examined on the merits.

*Claim Rejections - 35 USC § 112*

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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3. Claims 43, 44, 46, 47 and 50 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are drawn to a method of altering the amount of an unsaturated fatty acid in a seed of a plant by decreasing a fatty acid desaturase activity by transforming a plant with a sequence encoding a dominant negative mutant of a fatty acid desaturase. However, the only dominant negative mutant of a fatty acid desaturase that has been described in the specification is a fatty acid desaturase in which one or more of the essential histidine residues have been mutated. The specification does not describe what other structural changes could be made to a fatty acid desaturase which would result in a dominant negative mutant.

See *University of California v. Eli Lilly*, 119 F.3d 1559, 43 USPQ 2d 1398 (Fed. Cir. 1997), where it states:

"The name cDNA is not in itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding eDNA, there is no further information in the patent pertaining to that eDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin eDNA... Accordingly, the specification does not provide a written description of the invention..."

4. Therefore, given the lack of written description in the specification with regard to the structural and physical characteristics of the claimed compositions, one skilled in the art would not have been in possession of the genus claimed at the time this application was filed.

5. Claims 43-48 and 50 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

6. The claims are drawn to a method of altering the amount of an unsaturated fatty acid in a seed of a plant by decreasing a fatty acid desaturase activity by transforming a plant with a sequence encoding a dominant negative mutant of a fatty acid desaturase. However, the specification does not provide any examples of a plant that has been transformed with a sequence encoding a dominant negative mutant of a fatty acid desaturase that results in decreasing a fatty acid desaturase activity. In addition, the specification lacks guidance with regard to identifying sequences that would encode a dominant negative mutant of a fatty acid desaturase. De Luca teaches that modifying plant biosynthetic pathways by transforming plants with genes encoding enzymes involved in a pathway is highly unpredictable (see the paragraph bridging the columns on page 225N, for example), and that "on many occasions desired goals have been impossible to achieve" (see the last paragraph on page 228N). Thus, given the unpredictability of identifying sequences that are dominant negative mutants for fatty acid desaturases and for decreasing a fatty acid desaturase activity of a plant by transforming the plant with said sequence; the lack of guidance in the specification for identifying and characterizing any other sequences that are dominant negative mutants for fatty

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acid desaturases; given the lack of working examples of any dominant negative mutants for fatty acid desaturases that will decrease fatty acid desaturase activity in a plant; and the breadth of the claims, which encompass use of any dominant negative mutant genes of fatty acid desaturases to decrease fatty acid desaturase activity in any plant; and given the state of the art and the high level of skill in the transgenic plant art, it would require undue experimentation by one skilled in the art to make and use the invention as broadly claimed.

***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

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8. Claims 43, 44, 46 and 50 are rejected under 35 U.S.C. 102(e) as being anticipated by Lightner et al (U.S. Patent 6,372,965).

The claims are drawn to a method of altering the amount of an unsaturated fatty acid in a seed of a plant by decreasing a fatty acid desaturase activity by transforming a plant with a nucleic acid sequence encoding a mutant fatty acid desaturase.

Lightner et al teach a method of altering the amount of an unsaturated fatty acid in a seed of a plant by decreasing a fatty acid desaturase activity by genetic manipulation of a fatty acid desaturase, including by introduction of a recombinant construct comprising a nucleic acid sequence encoding a fatty acid desaturase into Glycine max, which is a soybean plant (see column 8, lines 34-50; columns 27-29; and columns 49-50, for example). Given the uncertainty with regard to what would constitute a mutant fatty acid desaturase, as stated above, the prior art patent anticipates the claims.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth F. McElwain whose telephone number is (571) 272-0802. The examiner can normally be reached on increased flex time.



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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Elizabeth F. McElwain, Ph.D.  
Primary Examiner  
Art Unit 1638

EFM